RESPONSE-10
K092493

MAR 29 2010

GPC Medical Ltd.

(BACKED BY EXPERIENCE SINCE 1990)

ISO 9001 ISO 13485 Certified WHO – GMP compliant CE

Premarket Notification 510(k) Summary As required by Section 807.92

General Company Information as required by 807.92 (a)

(a.1) The submitter's name, address, telephone number, a contact person, and the date the summary was prepared:

GPC Medical Limited
G-3 Vikas Puri, New Delhi 110 018
Telephone Number: +91-11-45545151
Contact Person: Vikas Narang

DATE: 3rd December 2009

(a.2) The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known

GPC Bone Plates and Bone Screws & **GPC** DHS/DCS Plate System

Common Name: THE SMOOTH OR THREADED METALLIC BONE FIXATION FASTENERS ARE CATEGORISED UNDER THE 21CFR TITLE 888.3040

888.3030 Plate-Fixation-Bone

THESE ALL DEVICES BELONG TO THE SAME REGULATION , i.e. 21 CFR TITLE 888.3030 & 888.3040

As these all devices belong to the same regulation and having same intended use-metallic bone plates and bone screws (fasteners), they have been bundled under the bundling of the devices.

(a.3) An identification of the legally marketed device to which the submitter claims equivalence

PREDICATE DEVICE: AS PER THE DETAILS GIVEN BELOW
NAME OF MANUFACTURER:
MICROWARE PRECISION CO.LIMITED
ADDRESS: No. 12, Keyuan, 2nd Rd. Situm district, Taichung City, 40763 Taiwan
MICROWARE THE BONE PLATES AND BONE SCREW SYSTEM AND DHS/DCS PLATE SYSTEM
510k Number for M/s Microware Precision Co. Limited

K072562

(a.4)A description of the device that is the subject of the premarket notification submission

DEVICE NAME-COMMON NAME: Bone Fixation Plate and Screw Including
SMOOTH OR THREADED METALLIC BONE FIXATION FASTENER
FIXATION BONE PLATES
APPLIANCES FOR FIXATION-SKELETAL PINS

DEVICES DECRIPTION:
THE BONE PLATES AND BONE SCREW SYSTEM AND DHS/DCS PLATE SYSTEM CONSIST OF NON-STERILE BONE PLANTE AND BONE SCREW IMPLANTS. THE PLATES ARE DEVICES WHICH ARE USED TO FASTEN THE BONES FOR THE PURPOSE OF FIXATION OF FRACTURED BONES. THE BONE PLATES CAN BE DISTINGUISHED IN TERMS OF THEIR FUNCTION, i.e. THE PLATE ON WHICH THIS IS TO BE FIXED.
Generally there are following types of bone plates:

- Dynamic Compression Type,
- Tubular Type
- Special (for particular bones)
- Mini fragment
- Used with Dynamic Hip screw and Used with Dynamic Condylar Screw

These bone plates are generally designed on the basis of the bone contour and anatomy.

GPC Medical Ltd. Tel.011-28541648, Fax:011-28560244

Following are further categories of bone plates:

S. No.	Type	Subtype
01	DCP	Small DCP, Narrow DCP, Lengthening Narrow, Broad DCP, Lengthening Broad Plates
02	Tubular Plates	Quarter Tubular, Semi Tubular and One Third Tubular Plates
03	Special Plates	L-Shaped, T-Shaped, Spoon, Lateral Tibial Head Buttress, Condylar Buttress, Hook, Cobra Head, Angled Plates for various Osteotomy locations. Reconstructions plates
04	Mini Fragment	Straight, L-Shaped, T-Shaped, condylar plates, reconstruction plates
05	DHS/DCS	DHS Barrel Plate with various angles and in short / large barrel length, DCS Plate

THESE DEVICE CAN BE MADE IN FOLLOWING MATERIALGRADES
STAINLESS STEEL ALLOY in compliance to ASTM F 138, ASTM F 139
TITANIUM ALLOY in compliance to ASTM F 136

- The GPC Bone Plates are divided mainly into

Mini Fragment Plate system
Small Fragment Plate System
Large Fragment Plate System
The thickness of these plates varies from 1.0mm to 6.0mm
The width of these plates varies from 3.0mm to 17mm
The length of these plates varies from 15mm to 360mm
The number of holes of these plates vary from 2 to 22 holes

- The GPC Bone Screws are differentiated by the manner in which they are fastened on the bone, their function, their size and the type of bone they are intended to be used for. Four Types of Screws;

Cortical (cortex) Screw
Cancellous Screw
Malleolar Screw
Cannulated

These screw variants can be provided with locking compression thread types as well as regular types.
Type of Recess: Hexagonal
Diameter Range: 1.5mm to 7.3mm
Length Range: 6mm to 150mm

- DHS / DCS Plate system consists of a DHS Plate or DCS Plate (Dynamic Hip Screw Type or Dynamic Compression Screw Type) This plate is fastened on femoral shaft using 4.5mm cortex screw (self tapping) and the barrel is fastened using DHS Screw having diameter ranging from 12.5mm to 14.0mm

Barrel Length: 25mm or 38mm
Barrel Angle: 95 degree, 135 degree, 140 degree, 145 degree, 145 degree and 150 degree
Compression is achieved using 4.0mm Diameter Compression Screw.

(a.5) A statement of the intended use of the device that is the subject of the premarket notification submission

Intended Use:

GPC Bone plates and bone screws are provided non-sterile. GPC bone plates and bone screws are intended for treating fractures of various bones including the clavicle, pelvis, scapula, long bone (humerus, ulna, radius, femur, tibia and fibula), and small bone (metacarpals, metatarsals, phalanges)

GPC DHS / DCS plate system is used to provide fixation of fractures to the proximal femur shaft and generally indicated for use in trochanteric, pertrochanteric, intertrochanteric and basilar neck fractures.

(b.1) (1) A brief discussion of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence;

GPC Bone Plates and Bone Screws & **GPC** DHS/DCS Plate System have been tested for the following non-clinical tests which have been performed to assess the performance of the devices according to the standards applied for conformance to the requirements.
Therefore **GPC** Bone Plates and Bone Screws & **GPC** DHS/DCS Plate System are safe and effective for the intended use.
The devices have been thoroughly tested through external laboratory as well in-house inspections for the specifications. Verification of compliance with the following mandatory and voluntary standards has been made.

GPC Metallic Bone Plates: Tested as per ASTM F 382 (US FDA Recognized Standards vide recognition number 11-214

GPC Metallic Angled Orthopaedic Fracture Fixation Devices: Tested as per ASTM F 384.

GPC Medical Smooth or Threaded Metallic Bone Fixation Fasteners: Tested as per ASTM F 543 (US FDA Recognized Standards vide recognition number: 11-210

Material Standards:
ASTM F 136: Specifications for wrought Titanium 6Al4V ELI Alloy UNS R 56401 for surgical implants
ASTM F 138: Specifications for wrought 18 Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implant
ASTM F 139

(b.3) Conclusion
The summary above shows that there are no new questions of safety and effectiveness for the **GPC** Bone Plates and Bone Screws & **GPC** DHS/DCS Plate System as compared to the predicate device. The performance and usability testing indicate that the **GPC** Bone Plates and Bone Screws & **GPC** DHS/DCS Plate System is substantially equivalent to the predicate device Microware the bone plates and bone screw system and DHS/DCS plate system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN - 4 2010

GPC Medical Limited
% Mr. Vikas Narang
Director - Exports
M-Block, DDA LSC,
Vikas Puri, New Delhi - 110018 (INDIA)

Re: K092493
Trade Name: GPC Bone Plates and Bone Screw & GPC DHS/DCS Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Codes: HRS, KTT; HWC
Dated: March 12, 2010
Received: March 17, 2010

Dear Mr. Narang:

This letter corrects our substantially equivalent letter of March 29, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092493

Device Name: GPC BONE PLATES AND BONE SCREWS

Indications For Use: GPC BONE PLATES AND BONE SCREWS ARE PROVIDED NON-STERILE. GPC BONE PLATES AND SCREWS ARE INTENDED TO TREAT FRACTURES OF VARIOUS BONES, INCLUDING THE CLAVICLE, PELVIS, SCAPULA, LONG BONES(HUMERUS, RADIUS, ULNA, FEMUR, TIBIA AND FIBULA), AND SMALL BONES-LIKE METALCARPALS, METATARSALS AND PHALANGES.

GPC DHS/DCS PLATE SYSTEM IS PROVIDED NON-STERILE. THE GPC DHS/DCS PLAT SYSTEM IS INTENDED FOR USE IN FIXATION OF FRACTURES OF THE PROXIMAL FEMUR. THE GPC DHS/DCS PLATE SYSTEM IS INDICATED FOR USE IN TROCHANTERIC, PERTROCHANTERIC, INTERTROCHANTERIC AND BASILAR NECK FRACTURE

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Brenn MD for MM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092493